K090020

SUMMARY

MAR 13 2009

Schiff & Company, located in West Caldwell, NJ and on behalf of Takara Belmont, USA, Inc., is submitting this 510(k) Premarket Notification for Bel-Cypher. The Bel-Cypher dental panoramic and cephalometric X-ray system is indicated for use as a generator of radiographic images of the dento-maxilofacial region and is intended for dental examination and diagnosis of diseases of the teeth, jaw, and oral structures.

Device Details:

Device Class:	CFR 872.1800 identifies the device as an Extraoral source x-ray system, Class II
Trade or Proprietary Name:	Bel-Cypher
Common or Usual Name:	System, X-ray, Extraoral source, digital
Classification Name:	Extraoral source x-ray system
Performance Standards:	IEC 60601-1-4 (Form D-019-1), IEC 60601-1-4 (1996), ISO 14971 (2007), IEC 60601-1-4 (Form D-018)
Labeling:	Copies are included with this submission.

Establishment Details:

Establishment Registration No: 96114485

Takara Belmont USA, Inc.
Belmont Equipment Division
101 Belmont Drive
Somerset, NJ 08873-1204

Performance Compliance:

IEC 60601-1-4 (Form D-019-1), IEC 60601-1-4 (1996), ISO 14971 (2007), IEC60601-1-4 (Form D-018)

Substantially Equivalent:

The Bel-Cypher is substantially equivalent to:

DEVICE NAME	510(K) NUMBER	MANUFACTURER
ANA-BEL	040748	Takara Belmont

Comparison of the Bel-Cypher to the ANA-BEL and Generic X-Ray Film/Screen appears in Attachment 3 of this submission.

Installation, operating instructions, care and maintenance are also included with this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 13 2009

TAKARA Belmont Corporation
% Mr. Kunihiko Sobue
Product Manager
TAKARA Belmont USA, Inc.
101 Belmont Drive
SOMERSET NJ 08873-1204

Re: K090020
Trade/Device Name: Bel-Cypher
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: January 2, 2009
Received: January 5, 2009

Dear Mr. Sobue:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K090020

Device Name: Bel-Cypher

Indicaiton for Use:

The Bel-Cypher dental panoramic and cephalometric X-ray system is indicated for use as a generator of radiographic images of the dento-maxilofacial region and is intended for dental examination and diagnosis of diseases of the teeth, jaw, and oral structures.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Offic of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K090020